

## REMARKS

In the Office Action mailed July 21, 2008, the drawings were objected to because there is no Figure 1a included in the set of drawings. The Examiner is informed that there is no Figure 1a, and Applicants have therefore cancelled from the specification the description of Fig. 1a that appears on page 6 at lines 18 and 19. Applicants now believe that the objection to the drawings has been rendered moot.

Claims 18-21 were also rejected under 35 U.S.C. §112, second paragraph, as being indefinite for the reasons set forth in numbered paragraph 4 of the Office Action mailed July 21, 2008, and the Examiner will please note that claims 18 and 19 have been amended to rectify the indefiniteness pointed out by the Examiner. Claims 13-16 and 18-21 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Champeau (U.S. Patent No. 6,208,881 B1). Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Champeau further in view of Houser et al. (U.S. Pub. No. 2002/0035361 A1). Claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Champeau further in view of Mulier et al. (U.S. Patent No. 6,537,248 B2). Claim 23 was rejected under 35 U.S.C. §103(a) as being unpatentable over Champeau in view of Mulier and further in view of Ellsberry et al. (U.S. Pub. No. 2001/0025176 A1). Claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over Champeau in view of Mulier et al. and further in view of Ellsberry et al. and the Livaditis article and further in view of Houser. For the reasons that follow, Applicants traverse the foregoing prior art rejections of claims 13-24, for the reasons that follow.

Claim 13 has been rejected as being unpatentable over Champeau (US 6,208,881) based on the Examiner's argument that Champeau discloses all the features of claim 13 except the pointed tip for piercing insertion, but the Examiner asserts that the pointed tip would be obvious to one of

ordinary skill in the art since the disclosure by Champeau of the structure of the catheter readily allows for a pointed tip shape to be created when it is formed and provides motivation to do such.

Applicants respectfully disagree with this reasoning, since Champeau clearly teaches in the opposite direction. Champeau teaches a flexible lead intended to conform to tissue structures and in particular to be steered through body cavities (see for example: abstract; column 1, lines 30-34; column 2, lines 62-65; column 6, lines 13-15). A pointed tip adapted for piercing insertion would be incompatible with such applications and insertion methods. There is clearly no suggestion or motivation in Champeau to provide a pointed tip since the catheter in Champeau is specifically designed with flexibility to follow body cavities or to be inserted through introducers or guide cavities (see column 6, lines 13-15).

Moreover, Champeau does not disclose at least two end electrodes arranged towards opposed ends of the catheter on either side of the pair of bipolar electrodes, said end electrodes adapted to function in monopolar mode. In Champeau, it is merely disclosed that the electrodes may function in either bipolar or monopolar mode, however there is no teaching of both bipolar and monopolar electrodes, and no teaching of at least two end monopolar electrodes on either side of a pair of bipolar electrodes. There would be no motivation in Champeau, or the other cited prior art, to realize the electrode arrangement according to the invention, since Champeau teaches the use of monopolar or bipolar only for ablation treatment. In the present invention, however, the monopolar electrodes at either end of the catheter are used for sealing treatment after piercing insertion (which is not the case in Champeau) and the bipolar electrodes for ablation treatment.

Furthermore, in Champeau the electrodes do not have the claimed feature “*supply channels adapted for the perfusion of saline solution*” (see Fig.1, 30,32,34,36 and 38, col 5, lines 6,7) since the electrodes have no holes to infuse saline. To the contrary, the infusion of saline exists through apertures independent of the electrodes in the catheter (see Fig.1, col 8, line 8,9).

Champeau thus does not disclose important features of the present invention as set forth in present claim 13, and moreover Champeau teaches in the opposite direction, and thus provides no motivation for the skilled person to modify Champeau to achieve the present invention according to claim 13.

Concerning claim 15, the Examiner asserts that the features thereof are disclosed in Champeau. While the applicants agree that Champeau discloses a plurality of lumens for supplying saline solution to various outlets on the flexible lead, there is absolutely no teaching in Champeau of independently supplying saline solution to the front/rear ends of the catheter and the liquid supply outlets proximate the center of the catheter. As far as can be understood, and as is known in the art, the plurality of lumens in Champeau are supplied with a common saline source, connected through a single Luer fitting (see col 8, line 6,7 and Fig. 1). This is disadvantageous over the presently claimed invention, since if several exits are connected to a unique Luer fitting, an incidental obstruction by a clot of tissue (which is frequent in Radiofrequency ablation while piercing the tissue) in one or more of the lumens will not cause the internal pressure of saline to change significantly, and thus may allow the continued operation with only certain exits of saline being functional. Separate independent supplies as proposed in the present invention reduces this problem.

There is no motivation for the skilled person in Champeau to have an independent supply, and moreover there is no suggestion whatsoever of having the front and rear ends with the saline supply independent of the intermediate outlets. It should be stressed that concluding that there would be a motivation in Champeau to have independent saline supply in the configuration as set forth in present claim 16 can only result from unallowable hindsight analysis, and knowledge of the present invention, since an important motivation from the claimed configuration comes from the piercing insertion and monopolar sealing electrode and bipolar ablation electrode combination, none of which is taught in Champeau.

Concerning claim 22, the Examiner has argued that Champeau discloses all the features of the claimed method, except for the actuation of the monopolar electrode proceeded by perfusion of saline and actuation of the bipolar electrodes, but that Mulier et al. discloses the criticality of a tight sealer on the puncture side, and therefore it would be obvious to the person of ordinary skill to supply RF energy to first seal the puncture using the electrodes functioning in monopolar manner and then supplying RF energy to bipolar electrodes for ablation. Applicants are of the opinion that this reasoning is not only incorrect, but is also based on unallowable hindsight analysis for the following reasons.

First, while Applicants admit that the need to limit saline outflow from the treatment area by having a sealing around the electrode is *per se* known, the teaching in Mulier is to provide a mechanical solution, whereby the helical needle more tightly engages the tissue, thereby providing a better seal between the tissue and the needle coils (see column 7, lines 15-26). This is a completely different solution to the one proposed in the present invention as claimed, and in fact the Mulier solution teaches in the opposite direction since the monopolar RF electrode sealing proposed in the present invention does not rely on a mechanical tightening of

the seal. If the skilled person adopts the Mulier sealing solution in Champeau, he just does not arrive at the present invention.

Further, there are other important differences between Champeau, Mulier and the presently claimed invention. For example, since there is no pointed tip and puncturing of tissue for insertion of the flexible lead disclosed in Champeau, this would clearly not lead the skilled person to adopt a sealing method that is well adapted to the needle puncturing catheter according to the present invention.

The remaining claims 23 and 24 are dependent on an allowable claim 22, and they should therefore also be allowable. Notwithstanding the foregoing, it must also be pointed out that the features of claim 23 are in the Applicants' opinion not disclosed in the prior art. Even though Ellsberry et al. discloses the use of different ionic saline solutions, there is no disclosure of having at least two independent saline supply solutions to modulate or to control the process. Therefore, even if the skilled person would consider combining the teachings of Champeau and Ellsberry, which is not admitted, he would still not arrive at the present invention as set forth in claim 23. Therefore, the features of claim 23 *per se* are non obvious over the cited prior art.

By: Clifford W. Browning  
Clifford W. Browning  
Reg. No. 32,201  
Krieg DeVault LLP  
One Indiana Square, Suite 2800  
Indianapolis, IN 46204  
(317) 238-6203